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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 1120661

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

03-BLT-25

September 15, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Keith Gore, Owner
Beach Smoke House
600 Norfolk Avenue
Virginia Beach, Virginia 23451

Dear Mr. Gore:

The Food and Drug Administration (FDA) inspected your firm, located at 600 Norfolk Avenue, Virginia Beach, Virginia, on July 14-18, 2003, and found that you have serious deviations from FDA's Fish and Fishery Products regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your smoked seafood products (Tuna, Mahi, Bluefish, and Salmon) to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). You can find the Act and seafood HACCP regulations through links on FDA's home page at www.fda.gov.

The deviations were as follows:

1. A deviation from a critical control point occurred when a batch of bluefish was smoked on 1/3/03 in that the batch was not heated to at least [redacted] minutes as required by your HACCP plan:
   a) Your firm failed to follow a corrective action plan already in place, or determine what corrective action needed to be taken. **21 CFR 123.7(a), 21 CFR 123.7(c)**
   b) Your firm failed to conduct a review of this record to ensure that critical control points were monitored and met or that corrective action was taken if a deviation occurred. **21 CFR 123.8(a)(3)**
   c) Your firm failed to document that corrective action was taken. **21 CFR 123.7(d)**

2. A deviation from a critical control point occurred when a batch of mahi mahi was smoked on 4/23/03 and cooling temperature was not monitored within [redacted] of the end of the cook. Your HACCP plan requires that cooling temperature be monitored within [redacted] of the end of the cook to determine if the fish has cooled to [redacted]F or less.
   a) Your firm failed to follow a corrective action plan already in place, or determine what corrective action needed to be taken. **21 CFR 123.7(a) and 21 CFR 123.7(c)**

b) Your firm failed to conduct a review of this record to ensure that critical control points were monitored and met or that corrective action was taken if a deviation occurred. **21 CFR 123.8(a)(3)**
c) Your firm failed to document that corrective action was taken. **21 CFR 123.7(d)**

3. Your firm's HACCP plan lists a monitoring procedure at a critical control point that is not adequate to control the hazard. Specifically, your procedure does not specify the need to document the receipt of frozen fish to verify that the temperature of the incoming product meets your HACCP plan requirement of not exceeding [redacted]F. Also, for shipments that are received on icc, your procedure does not specify how the temperature of [redacted] random fish is measured. **21 CFR 123.6(c)(4)**

4. Your HACCP plan failed to reference Clostridium botulinum as a hazard. **21 CFR 123.6(c)(i) and 21 CFR 123.16**

This is not an all-inclusive list of the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the seafood HACCP regulations (21CFR 123), and the Good Manufacturing Practice (GMP) regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all other applicable regulations.
We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days form your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response, documentation such as copies of your HACCP plans, monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Elizabeth A. Laudig, Compliance Officer at (410) 779-5441.

Sincerely,

Lee Bowers
Director, Baltimore District